BIOMET 3i

K122300

JAN 30 2013

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	BIOMET *3i*
Address	4555 Riverside Drive Palm Beach Gardens, Florida 33410
Phone number	(561) 776-6840
Fax number	(561) 514-6316
Establishment Registration Number	1038806
Name of contact person	Jacquelyn Hughes
Date prepared	January 17, 2012
Name of device	
Trade or proprietary name	*3i* T3 Dental Implant
Common or usual name	Endosseous Dental Implants
Classification name	Implant, Endosseous, Root-Form
Classification panel	Dental
Regulation	21CFR §872.3640
Product Code(s)	DZE
Legally marketed device(s) to which equivalence is claimed	K100724 OSSEOTITE® 2 Certain Implants K063341 Certain® Implants K051461 NanoTite® Implants K00321 ITI Dental Implant System
Reason for 510(k) submission	Addition to BIOMET *3i* dental implant product line to include an implant with a multi-level surface topography by adding a Calcium Phosphate (CaP) media-blasted roughened surface on the apical aspect of existing BIOMET *3i* Certain internal connection OSSEOTITE 2 (K100724) and internal connection Tapered (K063341) product lines.
Device description	The *3i* T3 Dental Implants are manufactured from Commercially Pure Grade 4 titanium and feature a roughened apex and traditional OSSEOTITE® coronal surface. The dental implants will consist of a straight wall or tapered body type with a basic screw-type design in various platform options and feature an internal connection/anti-rotation feature; 3.25 and 4/3mm has a 12pt dual hex; 4, 5, 6, 5/4 & 6/5mm has a six-point hex at the top and lower 12-point dual hex. The *3i* T3 Dental Implants are available with either the Prevail platform

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	switching feature or standard collar. In addition, the implants are offered with and without the nano-scale discrete crystalline deposition (DCD) calcium phosphate (CaP) surface treatment.
Intended use of the device	The *3i* T3 Dental Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.
Indications for use	BIOMET dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Summary of the technological characteristics of the device compared to the predicate

Characteristic	New Device	K100724	K063341	K051461	K003271
Description	3i T3 Dental Implants	Osseotite 2 Dental Implants	Certain Implants	Nanotite Implants	Dental Implant System
Material	CP4 Titanium (ASTM F67)	CP4 Titanium (ASTM F67)	CP Titanium (ASTM F) Ti -6AL-4V (ASTM F136)	CP Titanium (ASTM F67) Ti -6AL-4V (ASTM F136)	CP4 Titanium (ASTM F67)
Surface Finish	Grit Blast Acid-etch DCD	Acid-etch	Acid-etch	Acid-etch DCD	Grit Blast Acid-etch
Implant Design	Straight-Wall Tapered	Straight-wall	Straight-Wall Tapered	Straight-Wall Tapered	Solid self-tapping
Collar Design	Standard Prevail	Standard	Standard Prevail	Standard Prevail	Unknown
Diameter	Standard: 3.25- 6mm Prevail: 4/3-6/5mm	Standard: 3.25- 6mm	Standard: 3.25- 6mm Prevail: 4/3-6/5mm	Standard: 3.25- 6mm Prevail: 4/3-6/5mm	various
Length	8.5-18mm	8.5-18mm	7-20mm	8.5-20mm	various
Connection	Internal	Internal	Internal	Internal	External
Labeling	Sterile	Sterile	Sterile	Sterile	Sterile

PERFORMANCE DATA

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SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Performance Test Summary-New Device		
Characteristic	Standard/Test/FDA Guidance	Results Summary
3i T3 & *3i* T3 with DCD Implants - Cyclic Fatigue Testing	ISO 14801:2007	Cyclic Fatigue testing met indications
3i T3 & *3i* T3 with DCD Implants – Print Verification	Biomet *3i* procedure	Comparison of the original and design verification test models confirms the prints convey the design intent.

Comparative Performance Information Summary			
Characteristic	Requirement	New Device	Predicate Device
3i T3 vs. *3i* T3 with DCD Implants - Cyclic Fatigue Testing	Meet or exceed parameters	Meet	K100724
3i T3 with DCD Nano-Scale Calcium Phosphate Adhesion Strength	Meet or exceed parameters	Exceed	K051461
Tolerance Analysis *3i* T3 & *3i* T3 with DCD Implants – Tolerance Analysis	Meet or exceed parameters	Meet	K100724
3i T3 and *3i* T3 with DCD Implants – Torque Testing	Meet or exceed parameters	Meet	K100724
3i T3 & *3i* T3 with DCD Implants – Fit Check/ Mating Analysis	Meet or exceed parameters	Meet	K100724

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

Clinical Performance Data/Information: Data was provided from postmarket clinical studies of the predicate implants sponsored or supported by Biomet *3i*. Data on over 6,829 implants placed in the posterior from 1996 -2011 were available to demonstrate the difference in clinical survival rates for the various diameters of implants. None of the implant cases included fracture as an etiology for implant failure.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

No additional clinical testing was necessary for a determination of substantial equivalence.

The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 30, 2013

Ms. Jacquelyn A. Hughes, RAC
Director, Regulatory Affairs & Clinical Research
Biomet 3I
4555 Riverside Drive
PALM BEACH GARDENS FL 33410

Re: K122300
Trade/Device Name: 3i T3™ Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 9, 2013
Received: January 14, 2013

Dear Ms. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122300

Device Name: 3i T3™ Dental Implants

Indications For Use:

BIOMET 3i Dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.24 15:26:11 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122300